

MEMORANDUM OF CALL
Between Dr. Gilbert Leveille (McNeil Consumer Healthcare)
and Dr. Sharon Ross (DSNP, ONPLDS, CFSAN, FDA)
March 31, 2000 (5:30 pm)
Re: Petition for Health Claim: Plant Stanol Esters

A call was placed to Gilbert Leveille by Sharon Ross to ask that McNeil submit to FDA the even numbered pages for references 22, 23, and 24 of their submission (references 22-24 in the original petition are missing even numbered pages). References 22-24 are listed below:

22. McNeil Consumer Healthcare. Analytical Method 88-AM-601, Determination of Stanols and Sterols in Benecol Tub Spread. Fort Washington, PA 1999.

23. McNeil Consumer Healthcare. Analytical Method 88-AM-701, Determination of Stanols and Sterols in Benecol Soft Gels. Fort Washington, PA 1999.

24. McNeil Consumer Healthcare. Method Validation Report MV-88-AM-601, Determination of Stanols and Sterols in Benecol Tub Spread. Fort Washington, PA 1999.

Gilbert Leveille responded that he would submit complete copies of references 22-24 to the agency early next week.

00P-1276

MMH



McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034-2299 (215) 273-7000

APR 3 2000

Sharon A. Ross, PhD
Food & Drug Administration
Office of Nutritional Products,
Labeling and Dietary Supplements
HFS-830
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

**RE: McNeil Consumer Healthcare
Plant Stanol Esters Health Claim Petition
References 22, 23 & 24**

Dear Dr. Ross:

Per our conversation of Friday, March 31, 2000, enclosed are two complete copies of the Plant Stanol Esters Health Claim Petition references which you had identified as being incomplete:

Reference 22: McNeil Consumer Healthcare Analytical Method 88-AM-601,
Determination of Stanols and Sterols in Benecol[®] Tub Spread

Reference 23: McNeil Consumer Healthcare Analytical Method 88-AM-701,
Determination of Stanols and Sterols in Benecol[®] Softgels

Reference 24: McNeil Consumer Healthcare Method Validation Report MV-88-AM-601
Determination of Stanols and Sterols in Benecol[®] Tub Spread

Should you have any questions, please do not hesitate to contact me at 215/273-8194.

Sincerely,
MCNEIL CONSUMER HEALTHCARE

Gilbert A. Leveille
Worldwide Vice President,
Regulatory and Scientific Affairs

enc.

cc: L. A. Larsen, PhD (HFS-830)